REMARKS

This is in response to the Office Action that was mailed on September 27, 2002. Claims 1-12 have been amended to improve their form, and in some cases to address rejections under the second paragraph of 35 U.S.C. §112. New claims 13-22 have been added, directed to preferred embodiments of the invention that were previously recited in the original claim set. No new matter is introduced by this Amendment. Claims 1-22 are in the case.

Claims 1-12 were rejected under the second paragraph of 35 U.S.C. §112. It is respectfully submitted that the claims now before the Examiner are free of the informalities identified by the Examiner in former claims 1-12.

THE INVENTION. The present invention provides a method of producing a bioactive composite material for dental or orthopaedic use. The material comprises apatite, and contains groups with a tendency to decompose. In accordance with this invention, densification of the material is performed at high temperatures under pressure.

It has surprisingly been discovered that the reaction mechanism by which apatite undergoes decomposition in the oxide-hydroxyapatite system does not take place as it is conventionally presented in the literature. Instead, the decomposition takes place in two steps. In the first step, OH

groups in hydroxyapatite leave the structure, resulting in vacancies in the structure. When the number of vacancies exceeds a particular critical level, the resulting defective hydroxyapatite reacts with surrounding compounds, such as Al_2O_3, which catalyze the decomposition. Hydroxyapatite may be depicted as $Ca_{10}(PO_4)_6(OH)_2$ or as $Ca_5(PO_4)_3(OH)_1$. The two steps of the reaction are

$$Ca_5(PO_4)_3(OH)_1 \rightarrow Ca_5(PO_4)_3(OH)_{(1-y)}O_{y/2} + y/2\ H_2O$$

$$2\ Ca_5(PO_4)_3(OH)_{(1-y)}O_{y/2} + Al_2O_3 \rightarrow 3\ Ca_3(PO_4)_2 + CaAl_2O_4 + (1-y)\ H_2O$$

This type of decomposition takes place during densification/sintering of the material.

By changing the equilibrium reactions, decomposition may however be avoided. The present applicants find that this may be accomplished in three different ways, namely by decreasing the temperature in a closed system, by increasing the pressure, and/or by deliberately introducing the compounds to which the active compound strives to decompose. Thus, in accordance with the present invention, during densification/calcinations/sintering of material, a low sintering temperature should be used, **closing should take place early (before the actual sintering process begins)**, and **external pressure should be applied to the capsule before densification begins**.

According to the present invention, then, densification is performed in a closed system where application of pressure takes place partially or completely before an end temperature for the densification is reached and

before substantial decomposition of the apatite phase commences.

Claims 1-3, 5-7, and 12 were rejected under 35 U.S.C. §§102(b) or 103(a) as being anticipated by or unpatentable over US 5,306,673 (Hermansson). Hermansson discloses a hot isostatic pressing (HIP) process for a bioactive composite material, that is, a material which comprises groups with a tendency for decomposition. In the Hermansson process, densification of the material is performed at high temperatures under pressure. Hermansson describes a process in which raw compacts produced by cold isostatic pressing (CIP) are "encased in glass and densified by a hot isostatic pressing (HIP) **at a pressure of 200 MPa for 1 h at a maximum temperature of 925° C.** for the TiO_2-based materials and at 1225° C. for the other materials". Column 4, lines 14-19, emphasis supplied. As emphasized, Hermansson teaches only that the pressure is applied at the maximum temperature, not ***before*** the maximum temperature is reached. Hence Hermansson would not lead a person of ordinary skill in the art to the present invention, in which the pressure is partially or completely applied before an end temperature for the densification is reached and before commencing substantial decomposition of the apatite phase.

Claims 1, 4, and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over US 4,309,488 (Heide). Heide, similarly to Hermansson,

teaches that in HIP, "the mold is subjected to high gas pressure at elevated temperature". Column 5, lines 55-68. Hence, Heide teaches nothing about partially or completely applying the pressure before the "elevated" temperature is reached. There is absolutely no basis in the disclosure of the Heide patent for the Examiner's conclusion that "It is reasonable to conclude that Heide et al would not have used pressure and temperature conditions that cause substantial decomposition of the apatite phase". On the contrary, Heide did use conditions that cause decomposition, because of a lack of understanding of how temperature and pressure conditions effect decomposition!

Claims 8 and 9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hermansson or Heide in view of US 5,096,450 (Sugimura). Deficiencies of the Hermansson and Heide references have been discussed above. Sugimura is not directed to the manufacture of bioactive composite materials comprising groups with a tendency for decomposition, and hence does not relate to the same problem as does the present invention. However, Sugimura is illustrative of the conventional HIP process. Sugimura teaches in connection with Figure 5 that in a HIP process, the pressure is applied only after a substantial heating already has taken place. Column 3, lines 27-36. Hence, during the initial heating, up to 770°C, no pressure is applied.

SUMMARY. None of the cited references deals with the problem of decomposition of groups with a tendency for decomposition when producing a bioactive composite material, nor does any of the references teach a method to prevent such decomposition. Applicants do not contend that such decomposition problems were not known prior to the present invention, but Applicants do maintain that no one prior to the present invention had suggested or even hinted that the decompositions problems could be solved in the manner that is recited in the present claims. Applicants respectfully solicit withdrawal of all of the rejections of record and allowance of the application as amended herein.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,
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Attachment: Version With Markings Showing Changes Made

Serial No. 09/806,455
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VERSION WITH MARKINGS SHOWING CHANGES MADE

1. (amended) A method [Method] of producing a bioactive composite material, comprising apatite, for dental or orthopaedic use, which material comprises groups with a tendency for decomposition [(e.g. vaporization)], where a densification of the material is performed at high temperatures under pressure, characterized in that the densification is performed in a closed system where applying of pressure partially or completely takes place before an end temperature for the densification is reached, and before commencing substantial decomposition of apatite phase.

2. (amended) The method [Method according to] of claim 1, characterized in that said groups with a tendency for decomposition are hydroxyl, carbonate, phosphate, halogen or a combination thereof.

3. (amended) The method according to any of claim 1-2 [Method according to any of the preceding claims], characterized in that one phase in the material comprises a construction ceramic[, preferably an oxide, most preferably aluminium oxide, zirconium oxide or titanium oxide,] in a concentration of 10-95 vol-%[, preferably 40-95 vol-% and even more preferred 55-85 vol-%].

4. (amended) The method [Method] according to any of claims 1-2, characterized in that one phase in the material comprises a construction metal[, preferably Fe or Co-Cr based or Ti, Ta or Zr based,] in a concentration of 10-95 vol-%[, preferably 40-95 vol-% and even more preferred 55-85 vol-%].

5. (twice amended) The method of [Method according to] claim 1, characterized in that said composite material comprises hydroxyapatite and/or other apatite in a concentration of 5-80 vol%[, preferably 10-50 vol% and even more preferred 25-45 vol%].

6. (twice amended) The method of [Method according to] claim 1, characterized in that said closing of the system and applying of pressure takes place at temperatures below 900°C[,] for ceramic based composites [preferably below 800°C, even more preferred below 700°,] and for [more] metal based composites [preferably] below 500°C.

7. (twice amended) The method of [Method according to] claim 1, characterized in that said densification of the material is driven to an end temperature above 900°C[, preferably above 1000°C and even more preferred above 1100°C,] for ceramic based composites, or 500-800°C[, preferably 600-800°C] for metal based composites, and to an end pressure above 100 MPa[,

preferably up to 200 MPa].

8. (twice amended) The method of [Method according to] claim 1, characterized in that said applying of pressure is performed as a partial applying of pressure, before an end temperature for the densification is reached, and before commencing decomposition of apatite phase, whereby a part of pressure of 0.2-10 MPa is applied.

9. (twice amended) The method of [Method according to] claim 1, characterized in that said densification of the material is performed stepwise, whereby a first part pressure is applied[, preferably of about 0.2-5 MPa,] and is maintained up to a first temperature, whereafter a second part pressure is applied[, preferably of about 1-10 MPa,] and is maintained up to a second temperature, whereafter a possible further is applied, or an end pressure and an end temperature is applied.

10. (twice amended) The method of [Method according to] claim 1, characterized in that one or more helping agents are added to a barrier layer at densification by hot isostatic pressing or to a powder bed at densification by over pressure sintering, in order to further suppress unwanted reactions[, like decomposition and oxidation].

11. (amended) The method of [Method according to] claim 10, characterized in that said helping agent is a fine-grained metal powder and/or [an easily decomposing] a hydrate.

12. (twice amended) A bioactive [Bioactive] composite material, comprising apatite, for dental or orthopaedic use, which comprises groups with a tendency for decomposition [(e.g. vaporization)], characterized in that it has been produced by [to a method according to] the method of claim 1.